

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PUREWICK CORPORATION,)
)
 Plaintiff/Counterclaim Defendant,) **Redacted - Public Version**
)
 v.) C.A. No. 19-1508-MN
)
 SAGE PRODUCTS, LLC,) 
)
 Defendant/Counterclaim Plaintiff.) 

**PLAINTIFF'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO
EXCLUDE OPINIONS BY SAGE'S EXPERT THAT ARE
INCONSISTENT WITH THE COURT'S CLAIM CONSTRUCTION AND FOR
SUMMARY JUDGMENT OF INFRINGEMENT OF '376 PATENT CLAIMS 1 AND 9**

OF COUNSEL:
Steven C. Cherny
Brian P Biddinger
Matthew A. Traupman
Nicola R. Felice
Jason C. Williams
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
(212) 849-7000

Athena Dalton
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
191 N. Wacker Drive, Suite 2700
Chicago, IL 60606
(312) 705-7400

John W. Shaw (No. 3362)
Andrew E. Russell (No. 5382)
David M. Fry (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
arussell@shawkeller.com
dfry@shawkeller.com
Attorneys for Plaintiff

Dated: September 20, 2021

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PureWick Corporation (“PureWick” or “Plaintiff”) respectfully moves the Court for an order: 1) excluding opinions from Sage’s non-infringement expert that are inconsistent with the Court’s claim construction order and the plain and ordinary meaning of the claims; and 2) granting summary judgment of infringement of ’376 patent claims 1 and 9.

I. NATURE AND STAGE OF THE PROCEEDINGS

PureWick filed this action against Sage Products LLC (“Sage”) on August 8, 2019, accusing Sage of infringing the ’508 and ’376 Patents. D.I. 1. On October 2, 2019, PureWick filed a first amended complaint adding a claim that Sage infringes PureWick’s ’989 patent. D.I. 9. PureWick filed a second amended complaint on May 18, 2020, adding claims that Sage infringes the ’407 Patent. D.I. 44. On February 17, 2021, the Court issued a claim construction order (D.I. 128). Fact discovery closed April 16, 2021, and trial is scheduled to begin March 28, 2022.

II. SUMMARY OF THE ARGUMENT

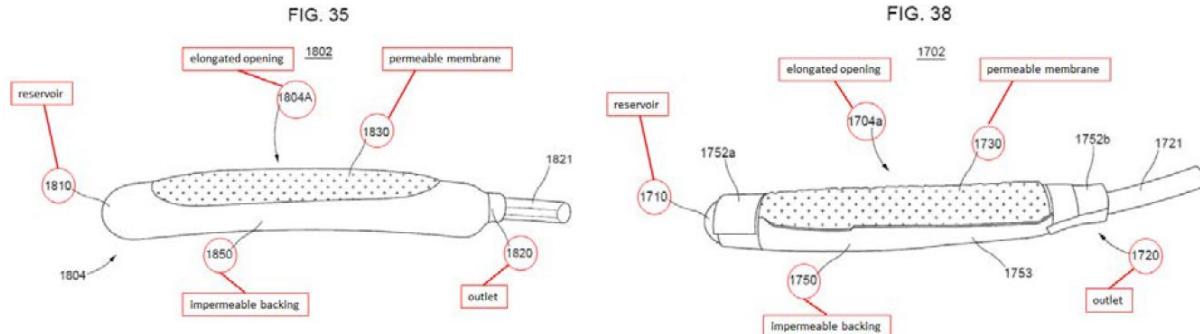
PureWick asserts that Sage’s PrimaFit product infringes claims 1, 4, 5 and 9 of PureWick’s ’376 patent. Sage asserts a number of defenses, but its assertions that it does not infringe claims 1 and 9 of the ’376 patent are based on the same erroneous claim construction arguments that the Court already rejected. There is no reason for the Court to allow Sage to improperly reargue its rejected claim construction arguments to the jury. Once the Court’s actual constructions are applied to the undisputed structure of Sage’s accused PrimaFit product there are no genuine disputes of material fact that the Sage product infringes claims 1 and 9. PureWick, therefore, asks the Court to enter summary judgment that PrimaFit infringes claims 1 and 9.

III. BACKGROUND

A. The Asserted '376 Patent

The '376 patent describes and claims external urine collection devices that may be used by persons who have “limited or impaired mobility such that typical urination processes are challenging or impossible.” D.I. 44-2 (“'376 Patent”) at 1:67-2:1. The devices described and claimed in the '376 patent generally include a fluid impermeable casing that has a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer between the reservoir and outlet. *Id.* at 4:48-51. The fluid impermeable layer defines an opening between the fluid reservoir and outlet, and there is a permeable membrane disposed over the opening. *Id.* at 4:50-53. The permeable membrane is supported by a permeable support that helps to maintain the shape of the membrane. *Id.* at 6:44-50. The devices are placed adjacent to the urethral opening so that urine flows through the permeable membrane into the device and into the fluid reservoir. *Id.* at 4:64-5:1. And there is a tube extending from the fluid reservoir to the fluid outlet for withdrawing urine from the device into a separate collection canister. *Id.* at 4:59-64.

The '376 patent discloses a number of different embodiments, including different versions of the fluid impermeable casing. In some implementations “the reservoir, the impermeable layer, and/or a portion of the outlet can be formed as an integral, one piece structure.” *Id.* at 22:16-18. In other implementations the casing is formed of separate components. *Id.* at 9:50-58; *see also* D.I. 105 at 50-53, 60-64. These different embodiments are reflected, for example, in claims 2 and 3, which respectively claim “[t]he apparatus of claim 1, wherein the casing is integrally formed of a polymer material,” and “the apparatus of claim 1, wherein the reservoir is formed of polymer and the fluid impermeable layer and fluid outlet are formed of elongate strips of adhesive tape.” '376 Patent at 36:37-41. Examples of these alternative embodiments of the casing are shown, e.g., in Figures 35 and 38 of the '376 patent:



D.I. 105 at 63.

B. The Court's Claim Constructions

During claim construction the parties disputed the meanings of a number of terms, with Sage often advancing constructions divorced from the ordinary meanings of well-known terms such as “wicking,” or advancing constructions supported by the results it sought as opposed to the intrinsic record. On February 2, 2021, the Court held a hearing and resolved the construction of several disputed terms, including two terms from the ‘376 patent relevant to the present motion.

Specifically relevant to this motion, the parties disputed the construction of the limitation in claim 1 requiring a “casing having a fluid reservoir at a first end [and] . . . , a fluid outlet at a second end” Sage argued that the phrase should be construed as follows:

A casing secures a filling [in this case a permeable support] by surrounding and enclosing it at least partially on all sides. The casing has [or defines], among other things, a fluid reservoir and a fluid outlet. A backing/impermeable layer in combination with securing portions for other components is not a casing.

D.I. 105 at 48. According to Sage, the ‘376 patent allegedly “distinguish[ed] the casing embodiments, where the support and membrane are inserted into the casing, from the ‘backing’-type embodiments with securing mechanisms (such as tape) to hold the backing and rest of the device together.” *Id.* at 57-58. Thus, Sage argued that the embodiments in Figures 36-38 should be excluded from the claims through a negative limitation that “[a] backing/impermeable layer in combination with securing portions for other components is not a casing.” *Id.* at 53, 56-58.

The Court rejected Sage’s arguments and “agree[d] with Plaintiff that the claim term does not require reading in the limitations (or negative limitation) Defendant proposes.” D.I. 128 at 11. The Court explained further that there was “no . . . express disclaimer or lexicography in the pieced-together different parts of the specification and prosecution that Defendant cites.” *Id.* at 12. The Court therefore construed the phrase “casing having a fluid reservoir at a first end [and] . . . , a fluid outlet at a second end . . . ” to mean “an outer cover having a fluid reservoir at a first end and a fluid outlet at a second end.” D.I. 128 at 2.

Also relevant here, the parties disputed the construction of the term “wicking material,” which appears in claim 9 of the ’376 patent. Sage contended that the term should be construed to mean “an article that includes a permeable material with a high absorption and permeation rate, such as gauze, felt, terrycloth, thick tissue paper, and paper towel.” D.I. 128 at 8.¹ According to Sage, the moisture-wicking materials in the ’376 patent had to be “absorptive and permeable” because the patent allegedly found those two properties “essential.” D.I. 105 at 39.

The Court again rejected Sage’s proposed construction and construed “wicking material” to mean “an article that moves moisture by capillary action from one surface of the article to the other.” D.I. 128 at 1-2. The Court explicitly rejected Sage’s construction that “improperly conflate[d] the property of ‘wicking’ with the separate properties of absorption and permeation” because, “although materials can provide for wicking, absorption and permeation,” these are different properties . . . [a]nd the patents treat them as different properties.” *Id.* at 9.

C. Sage’s Non-Infringement Positions

On February 12, 2020, PureWick served an interrogatory asking Sage to set forth the bases

¹ As the Court noted in its Claim Construction Order, the parties agreed that the ordinary meaning of “wicking” is “moving moisture from one surface to another surface by capillary action,” but Sage argued that the patents defined the term differently. *Id.*; *see also* D.I. 105 at 39.

for its contention that the PrimaFit product does not infringe, *inter alia*, the '376 patent. PureWick expressly requested that Sage “identify[] each limitation in each claim that Defendant contends the Accused Product does not infringe.” Ex. 1 at 9. In response to that interrogatory, Sage stated that [REDACTED] [REDACTED] “ and that [REDACTED] [REDACTED] ” *Id.* at 13. Sage did not allege that the PrimaFit lacked a wicking material, as required by claim 9 of the '376 patent. *Id.*

After the Court’s claim construction ruling, Sage amended its response to PureWick’s interrogatory. Oddly, Sage made no attempt to apply the Court’s construction of the phrase “casing having a fluid reservoir at a first end [and] . . . , a fluid outlet at a second end” Instead, Sage repeated verbatim the same bland statement it made in its original response before claim construction: [REDACTED] [REDACTED] ” Ex. 2 at 19. Sage additionally referenced a May 15, 2020 letter from counsel for Sage to counsel for PureWick where it asserted the recently rejected argument that “[t]he patents distinguish between a device with a ‘backing’ and a device with a ‘casing.’” *Id.* at 24.

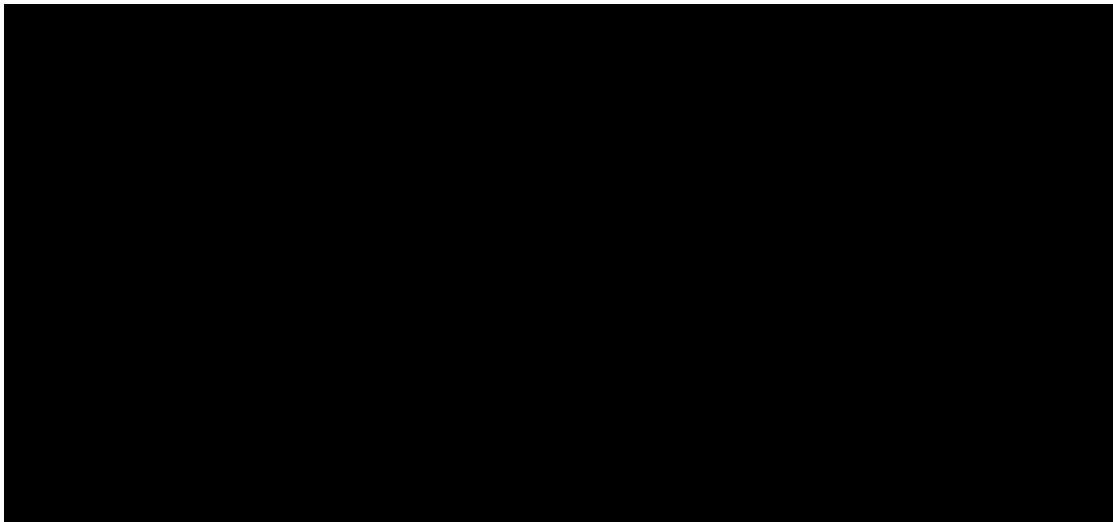
Additionally, Sage stated for the first time that, with respect to claim 9 of the '376 patent, [REDACTED] [REDACTED] .” *Id.* at 20. Again, Sage made no attempt to explain how it could maintain this position given the Court’s recent construction of “wicking material.”

D. Infringement By The PrimaFit Product

Consistent with the Court’s constructions of, *inter alia*, “casing” and “wicking material,” PureWick’s expert, Dr. John Collins, opined in his opening and reply expert reports, incorporated

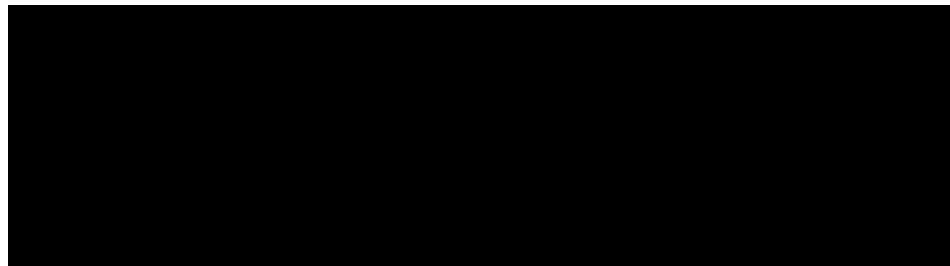
herein by reference, that each element of claims 1 and 9 of the '376 patent is present in the PrimaFit product. Ex. 3 at ¶¶ 189-207, Collins Ex. E, pp. 1-14; *see also* Ex. 4 at ¶¶ 95-142, 156-58.

Dr. Collins showed that the PrimaFit includes a casing formed from the fluid reservoir cap, the [REDACTED] backing, and the top and bottom [REDACTED] adhesive strips, all shown below. Ex. 3 at Ex. E, p. 1; Ex. 15.



He also opined that the PrimaFit included a wicking material, labeled above as a “[REDACTED] [REDACTED].” Ex. 3 at Ex. E, pp. 29-33; Ex. 4 ¶¶9-28.

Dr. Collins also showed that the PrimaFit includes a fluid permeable support, labeled below as the “[REDACTED].” The “[REDACTED]” is inside the PrimaFit device and is covered partially by the “[REDACTED],” shown above. The PrimaFit device also includes a tube extending from the fluid reservoir to the outlet at the other end of the device, as shown in the below drawing.



See Ex. 3 at Ex. E, pp. 3-6; Ex. 5 at 2.

IV. LEGAL STANDARD

Summary judgment should be granted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A fact is genuinely disputed only “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). “The moving party bears the burden of demonstrating the absence of a genuine issue of material fact.” *Biomerieux, S.A. v. Hologic, Inc.*, C.A. 18-21-LPS, 2020 WL 759546, at *3 (D. Del. Feb. 7, 2020). “If the moving party has carried its burden, the nonmovant must then ‘come forward with specific facts showing that there is a genuine issue for trial.’” *Id.* (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986)). “To defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.”” *Id.*

V. ARGUMENT

The structure of the accused Sage PrimaFit device is not in dispute. Sage’s original non-infringement positions, set forth in its various interrogatory responses, consisted of little more than conclusory anodyne assertions that elements were missing with little explanation or attempt to apply the Court’s constructions. Sage now advances non-infringement positions in the rebuttal expert report of Donald Sheldon that are based on the same claim construction positions the Court rejected, or that are inconsistent with the plain and ordinary meaning of the claims and that Sage never raised during the claim construction phase of this case. Those opinions should be excluded as unreliable and contrary to law. *See EMC Corp. v. Pure Storage*, 154 F. Supp. 3d 81, 99 (D. Del. 2016) (“No party may contradict the court’s construction to a jury.”) (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009)); *Intuitive Surgical, Inc. v. Auris Health, Inc.*, C.A. 18-1359-MN, 2021 WL 3033396 at *4 (D. Del. July 19, 2021) (“Auris’s attempt

to introduce claim construction through expert testimony is improper.”). Put simply, Sage should not be permitted to collaterally attack what this Court already has decided at claim construction, nor should it be allowed to rely on new, “belated claim construction arguments” under the guise of an expert’s non-infringement positions. *Intuitive Surgical*, 2021 WL 3033396 at *4. Once Mr. Sheldon’s inadmissible opinions are excluded, there is no genuine dispute that the accused Sage PrimaFit product infringes at least claims 1 and 9 of the ‘376 patent.

A. Sage's Non-Infringement Arguments For '376 Patent Claim 1 Are Inconsistent With The Court's Claim Construction Order And PureWick Is Entitled to Summary Judgment of Infringement of That Claim

1. [1A] An apparatus comprising: a fluid impermeable casing having a fluid reservoir at a first end, a fluid outlet at a second end, and a longitudinally extending fluid impermeable layer coupled to the fluid reservoir and the fluid outlet and defining a longitudinally elongated opening between the fluid reservoir and the fluid outlet

Dr. Collins opined that the Sage PrimaFit meets element [1A] of claim 1. *See* Ex. 3 at Ex. E, pp. 1-3. Mr. Sheldon’s responsive non-infringement opinions mirror Sage’s claim construction arguments concerning “casing” that already were considered and rejected by the Court, or rely on improper new claim construction positions.

First, Mr. Sheldon argues that the PrimaFit device “

.” Ex. 6 at 71. He argues that

¹⁰ *Id.* at 74. *This is the same*

argument Sage made in its claim construction brief that the Court already rejected. D.I. 105 at 56. Indeed, Mr. Sheldon's opinion that a [REDACTED] “

is not a casing (Ex. 6 at 70) is no different than Sage's prior argument that "a 'backing/impermeable layer in combination with securing portions for other components,' is not a casing." D.I. 105 at

60. Claim 1 of the '376 patent does not impose any limitation on how many components are used to make the casing, nor prohibit the casing from being formed from an end cap, a backing and strips of tape. In fact, as pointed out during claim construction, the casing in Fig. 38 of the '376 patent is formed from an end cap, a backing and strips of tape. '376 Patent at 27:10-36.²

Second, Mr. Sheldon argues that [REDACTED]

[REDACTED].” Ex. 6 at 68. He relies on portions of the '376 patent, contending they “[REDACTED].” *Id. Once again, Sage made this same argument during claim construction* (D.I. 127 at 76:25-77:6, 77:11-13; D.I. 105 at 57-58) and the Court rejected it, holding that “[t]he specification has some embodiments in which the permeable support is in the casing, but the claims do not have language that requires that” and “the specification references embodiments in which the casing surrounds the permeable membrane, but the claims do not require that.” D.I. 128 at 12.

Third, Mr. Sheldon argues that the PrimaFit device does not include “a longitudinally elongated opening between the fluid reservoir and the fluid outlet.” Ex. 6 at 76-77. According to Mr. Sheldon, [REDACTED]

² Anomalously, despite his effort to exclude that embodiment from the claims in his non-infringement report, [REDACTED]. During his deposition, Mr. Sheldon testified that [REDACTED]. Ex. 7 at 99:13-100:2, 102:7-103:23. Mr. Sheldon also stated in his report that [REDACTED] Ex. 14 at 216. If, as Mr. Sheldon contends, [REDACTED] then Figure 38 necessarily has a fluid impermeable casing and Sage's renewed attempt artificially to exclude that embodiment from the claims should be rejected.

Ex. 6 at 77. Mr. Sheldon’s opinion is a rehash of Sage’s rejected claim construction arguments, and an attempt to limit the claims to exemplary embodiments from the specification. In support of its rejected “casing” construction, Sage argued that its construction was supported by the specification’s disclosure of a permeable support and membrane that could “be inserted through the elongated opening of the casing.” *See* D.I. 127 at 77:3-6. Again, the Court rejected Sage’s construction because, like Mr. Sheldon, Sage was attempting to limit the scope of the claims based on exemplary embodiments. D.I. 128 at 12.

Indeed, although the ‘376 patent discloses embodiments where the permeable support and membrane are “inserted through the elongated opening of the casing,” it also discloses embodiments where the elongated opening of the casing is formed with a backing that is secured to the permeable support and membrane with tape. ‘376 Patent at 27:10-17. The elongated opening in the PrimaFit device is no different than the elongated opening of Figure 38 in the ‘376 patent. *Compare* Ex. 3 at Ex. E, p. 3, *with* § III.A. at 3, *supra*, *and* ‘376 Patent at 27:10-17. As with the PrimaFit, the opening in Figure 38 is covered by a fluid permeable membrane that is affixed to the impermeable backing by adhesive. *See* § III.A. at 3, *supra*; ‘376 Patent at 27:17-20, 23-26. Moreover, contrary to Mr. Sheldon’s opinions the ‘376 patent expressly discloses that the permeable membrane can be attached to the backing. *See* ‘376 Patent at 9:53-58, 13:54-63 (“[T]he impermeable layer 150 can be formed of . . . elongate strips of an adhesive tape, wrapped around at least a portion . . . of the permeable membrane 130.”); *id.* at 13:54-63 (“[t]he permeable membrane 230 can be secured in place with one or more securing elements 252,” which “can be impermeable and form a portion of or all of an impermeable layer”). Thus, Mr. Sheldon’s opinions are not only a rehashing of Sage’s previously rejected claim construction arguments, they also are

improper to the extent that he is advancing new interpretations of the claims that are inconsistent with the intrinsic evidence and with the law. *See Intuitive Surgical*, 2021 WL 3033396 at *4.

Finally, Mr. Sheldon argues that the PrimaFit [REDACTED]

[REDACTED] Ex. 6 at 74.

Mr. Sheldon points to [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] *Id.* at 43, 75. Mr. Sheldon argues that [REDACTED]

[REDACTED] *Id.* at 44. This argument was never raised in Sage's non-infringement interrogatory response and is untimely. And it also is directly contrary to the '376 patent's specification and claims. The '376 patent discloses embodiments of a fluid impermeable casing that have vacuum relief openings. *See* '376 Patent at 26:19-20 ("The impermeable casing can also include a vacuum relief opening 2058."). It is clear, therefore, that

[REDACTED]

[REDACTED]. Mr. Sheldon's arguments therefore fail to create a material dispute with regard to element [1A].

2. [1B] a fluid permeable support disposed within the casing with a portion extending across the elongated opening, wherein the fluid permeable support is distinct from and at least proximate to the fluid reservoir

Dr. Collins opines that Sage's PrimaFit meets element [1B] of claim 1. *See* Ex. 3 at Ex. E, pp. 3-6. In response, Mr. Sheldon once again repeats arguments that the Court considered and rejected during claim construction, or belatedly advances new, previously undisclosed contentions that are improper and inconsistent with the intrinsic evidence.

Mr. Sheldon contends that [REDACTED]

[REDACTED] Ex. 6 at 78. This, again, is a rehash of Sage's rejected claim construction arguments. *See* D.I. 127 at 77:2-13, 83:3-5. As the Court recognized, claim 1 of the '376 patent does not require that the permeable support be inserted into the casing. *See* D.I. 128 at 12. Indeed, like the PrimaFit, the fluid permeable support in Fig. 38 is between the fluid permeable membrane and impermeable backing, and the casing components are taped together around the support. *See* supra § III.A. at 3.

Additionally, Mr. Sheldon argues that [REDACTED]

[REDACTED] Ex. 6 at 81. This is a position that Sage never advanced in its non-infringement interrogatory contentions. *See* Ex. 2 at 19-20. In any event, Mr. Sheldon offers no support for his opinion, stating only that [REDACTED]

[REDACTED] *Id.* Mr. Sheldon since admitted at his deposition [REDACTED], which is readily apparent from even a casual observation of the device. *See* Ex. 7 at 202:24-25 [REDACTED]

[REDACTED]). And it is equally apparent that the reservoir (formed by the end cap) is distinct from the permeable support (the batting material). To the extent that Mr. Sheldon believes otherwise, his opinion is contrary to the '376 patent, which describes and depicts a reservoir defining an empty space for collecting urine that is distinct from, yet proximate to, the material defined as the permeable support. '376 Patent at 24:6-8, Fig. 32. Exactly like the '376 patent, the PrimaFit device also has a reservoir—in the end cap—which defines an empty space for collecting urine that is distinct from, yet proximate to, the fabric batting material identified as the fluid permeable support. *See* Ex. 3 at Ex. E, pp. 3-4; Ex. 8 ([REDACTED]

█████). Mr. Sheldon has thus failed to create a factual dispute with regard to element [1B].

3. [1C] a fluid permeable membrane disposed on the support and covering at least the portion of the support that extends across the elongated opening, so that the membrane is supported on the support and disposed across the elongated opening

Dr. Collins opined that the Sage PrimaFit meets element [1C] of claim 1. *See* Ex. 3 at Ex. E, pp. 6-8. In response, Mr. Sheldon offers more opinions that restate rejected claim construction arguments.

Mr. Sheldon argues that

Ex. 6 at 82. According to Mr. Sheldon,

Id. He thus contends that

As explained above, *see supra* §§ III.B, V.A.1, Sage made a similar argument during claim construction in support of its proposed construction of “casing,” which the Court rejected.³ Indeed, claim 1 does not require that the permeable membrane be disposed on a fluid permeable support and then inserted into a casing. The claim does not have any requirement at all about the manner in which the device is assembled. Moreover, there is nothing in either the claims or the

³ Sage argued during claim construction that “the patents expressly distinguish the casing embodiments, where the support and membrane are inserted into the casing, from the “backing”-type embodiments with securing mechanisms (such as tape) to hold the backing and rest of the device together.” D.I. 105 at 57-58 (emphasis in original). It thus argued for a proposed construction with a negative limitation: “A backing/impermeable layer in combination with securing portions for other components is not a casing.” D.I. 128 at 11. The Court found no support for Sage’s proposed construction. *Id.* at 12.

specification that prevents the fluid permeable material from being supported on the permeable support while also being attached or affixed to part of the casing.

Mr. Sheldon also asserts that [REDACTED]

[REDACTED]

[REDACTED] Ex.

6 at 83. Mr. Sheldon's argument was never included in Sage's non-infringement interrogatory responses. Ex. 2 at 19-20. It also relies again on a new and belated claim construction position that improperly reads a requirement into claim 1 of the '376 patent (that the fluid permeable membrane must be positioned dependent on the fluid permeable support) that does not exist. The claim only requires that the membrane is "disposed on the support and covering *at least the portion of the support that extends across the elongated opening*, so that the membrane is supported on the support and disposed across the elongated opening." '376 Patent at 36:20-24 (emphasis added). Thus, regardless of the fact that the fluid permeable membrane is sewn to the fluid impermeable backing, the membrane is still disposed on the support and covering at least a portion of the support that extends across the elongated opening such that the membrane is supported on the support and disposed across the elongated opening. Mr. Sheldon's arguments therefore fail to create a factual dispute with regard to element [1C].

4. [1D] **a tube having a first end disposed in the reservoir and extending behind at least the portion of the support and the portion of the membrane disposed across the elongated opening and extending through the fluid outlet to a second, fluid discharge end**

Dr. Collins opined that that the Sage PrimaFit meets element [1D] of claim 1. *See* Ex. 3 at Ex. E, pp. 8-11. Mr. Sheldon does not dispute that the PrimaFit meets this claim element. *See generally* Ex. 6 at pp. 66-83.

5. [1E] **the apparatus configured to be disposed with the opening adjacent to a urethral opening of a user, to receive urine discharged**

from the urethral opening through the opening of the fluid impermeable layer, the membrane, the support, and into the reservoir, and to have the received urine withdrawn from the reservoir via the tube and out of the fluid discharge end of the tube.

Dr. Collins opined that that the Sage PrimaFit meets element [1E] of claim 1. *See* Ex. 3 at Ex. E, pp. 11-14. Mr. Sheldon does not dispute that the PrimaFit meets this claim element. *See generally* Ex. 6 at pp. 66-83.

Mr. Sheldon’s non-infringement positions regarding claim 1 of the ’376 patent disregard the Court’s construction of the “casing” claim limitation, rehash arguments made and rejected at the claim construction stage, and seek to read requirements into the claim that do not exist. Mr. Sheldon’s positions fail to create a factual dispute regarding infringement of claim 1 for the reasons laid out above. Thus, PureWick is entitled to summary judgment of infringement of claim 1 of the ’376 patent by Sage’s PrimaFit product.

B. Sage’s Non-Infringement Arguments For ’376 Patent Claim 9 Are Inconsistent With The Court’s Claim Construction Order And PureWick Is Entitled To Summary Judgment Of Infringement of That Claim

Dependent claim 9 of the ’376 patent adds the requirement that the fluid permeable membrane includes “a wicking material.” PureWick has offered uncontroverted evidence that [REDACTED]

[REDACTED]
[REDACTED] *See* Ex. 3 at ¶ 195, Ex. E, pp. 29-33; Ex. 4 at ¶¶ 9-28.

For example, Sage’s documents establish that [REDACTED]

[REDACTED] Ex. 9 at 10

(emphasis added). [REDACTED]

[REDACTED] *Id.*; Ex. 10 [REDACTED]

[REDACTED] [REDACTED] (emphasis added); *see also* Ex. 11 at 1-2 (same). [REDACTED]

[REDACTED]
[REDACTED] Ex. 12. Sage also produced documents

[REDACTED] Ex. 13 at

2. Based on this incontrovertible evidence, Dr. Collins opined that that the Sage PrimaFit meets claim 9 of the '376 patent. *See* Ex. 3 at Ex. E, pp. 29-33. Indeed, Sage never asserted in their interrogatory response that the PrimaFit did not have a wicking material, only that “[REDACTED]

[REDACTED]” Ex. 2 at 20.

In his responsive report, Mr. Sheldon ignores the Court’s construction of the term “wicking material” and bases his opinion instead on what he alleges to be “[REDACTED]

[REDACTED]” Ex. 6 at 27. According to Mr. Sheldon, [REDACTED]

[REDACTED] *Id.* at 23-25. First, neither PureWick nor Dr. Collins have ever taken the position that an absorbent fabric cannot also be a wicking material—in fact, Dr. Collins has expressly stated the opposite. *See* D.I. 107-6 at ¶ 41 (“Although some materials can provide for wicking, absorption and permeation, these are different properties.”). Of course, post-construction, PureWick’s alleged view of the term is entirely irrelevant. And, as both parties discussed during claim construction, the asserted patents give examples of several materials that no one disputes are both absorbent and wicking, including, e.g., paper towels, felt and gauze. *See* D.I. 44-1 (“‘508 patent”) at 4:10-12; '376 Patent at 6:22-25. Consistent with PureWick’s positions, the Court did not construe the term moisture wicking to

exclude absorbent materials. Rather, the Court construed the term consistent with the fact that wicking and absorbency are different properties.

Notwithstanding the Court's construction, Mr. Sheldon contends that [REDACTED]

[REDACTED]. Ex. 6 at 24-25. Notably, [REDACTED]

[REDACTED] *Id.* at 26.

The fact that [REDACTED], however, is immaterial to whether it wicks pursuant to the Court's claim construction. Indeed, even Mr. Sheldon acknowledged in his reply invalidity report that " [REDACTED]" Ex. 14 at p. 5. Because Mr. Sheldon's non-infringement opinion is inconsistent with the Court's construction, it should be rejected. Mr. Sheldon's arguments fail to create a factual dispute with regard to claim 9, and PureWick is therefore entitled to summary judgment of infringement of that claim.

VI. CONCLUSION

For the foregoing reasons, PureWick respectfully requests that the Court grant its motion to strike Mr. Sheldon's improper claim construction opinions, and for summary judgment of infringement of claims 1 and 9 of the '376 patent.

OF COUNSEL:

Steven C. Cherny
Brian P Biddinger
Matthew A. Traupman
Nicola R. Felice
Jason C. Williams
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
(212) 849-7000

/s/ John W. Shaw

John W. Shaw (No. 3362)
Andrew E. Russell (No. 5382)
David M. Fry (No. 5486)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
arussell@shawkeller.com
dfry@shawkeller.com
Attorneys for Plaintiff

Athena Dalton
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
191 N. Wacker Drive, Suite 2700
Chicago, IL 60606
(312) 705-7400

Dated: September 20, 2021

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on September 20, 2021, this document was served on the persons listed below in the manner indicated:

BY EMAIL

Anne Shea Gaza

Samantha G. Wilson

YOUNG, CONAWAY, STARGATT &
TAYLOR LLP

Rodney Square

1000 North King Street
Wilmington, DE 19801

(302) 571-6727

agaza@ycst.com

swilson@ycst.com

Robert A. Surrette

Sandra A. Frantzen

Christopher M. Scharff

Ryan J. Pianetto

Paul W. McAndrews

Deborah A. Laughton

MCANDREWS, HELD & MALLOY, LTD

500 West Madison Street

Chicago, IL 60661

(312) 775-8000

bsurrette@mcandrews-ip.com

sfrantzen@mcandrews-ip.com

cscharff@mcandrews-ip.com

rpianetto@mcandrews-ip.com

pwmcandrews@mcandrews-ip.com

dlaughton@mcandrews-ip.com

/s/ John W. Shaw

John W. Shaw (No. 3362)

David M. Fry (No. 5486)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor

Wilmington, DE 19801

(302) 298-0700

jshaw@shawkeller.com

dfry@shawkeller.com

Attorneys for Plaintiff

Exhibit 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PUREWICK CORPORATION,

Plaintiff and Counterclaim Defendant,

v.

SAGE PRODUCTS, LLC,

Defendant and Counterclaim Plaintiff.

C.A. No. 19-1508-MN

**MAY CONTAIN CONFIDENTIAL
INFORMATION**

**DEFENDANT'S FIRST SUPPLEMENTAL OBJECTIONS AND RESPONSES TO
PLAINTIFF'S FIRST SET OF INTERROGATORIES (NOS. 1-6) AND
DEFENDANT'S OBJECTIONS AND RESPONSES TO
PLAINTIFF'S SECOND SET OF INTERROGATORIES (NOS. 7-12)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendant and Counterclaim Plaintiff Sage Products, LLC (“Sage”) hereby supplements its objections and responses to Plaintiff’s Interrogatory Nos. 1-6 and hereby objects and responds to Plaintiff’s Second Set of Interrogatories to Defendant (Nos. 7-12).

GENERAL OBJECTIONS

1. Sage hereby incorporates its General and specific objections set forth in its initial responses to Plaintiff’s First Set of Interrogatories to Defendant and First Set of Requests to Defendant for the Production of Documents and Things.

2. Sage further objects to the definition of “Accused Product” as vague, overly broad, and unduly burdensome to the extent that it includes products other than Sage’s PrimaFit® product and Sage’s PrimoFit™ product identified in Plaintiff’s Second Amended Complaint (D.I. 44), as Plaintiff has not identified any other “Accused Product” with any specificity and has not provided any relevant disclosures pursuant to the Case Scheduling Order or the Default Standard. Sage

agreement. Again, PureWick never referenced any patent issues, never alleged infringement of the 508 patent (which had issued years earlier), never mentioned any infringement of the now newly-issued 376 patent, and never referenced any potential patent infringement issues relating to any pending patent applications. Thus, in multiple pieces of correspondence with Sage relating to the PrimaFit® product over several years prior to the filing of the Complaint, PureWick never alleged any patent infringement issues (while simultaneously and wrongly requesting information about other potential alleged violations such as, e.g., use of confidential information). PureWick's actions and inactions led Sage to believe that PureWick did not believe the PrimaFit® product infringed any PureWick patents.

As explained, Plaintiff did not notify Sage of any alleged infringement until it filed its Complaint and Amended Complaint on August 12, 2019, and October 2, 2019, respectively. The Complaints failed to present *prima facie* cases of infringement. Sage filed its response to the Amended Complaint on November 1, 2019, in which it detailed numerous good faith defenses to Plaintiff's claims including detailed explanations of why no valid claim of any Patent-In-Suit is infringed as well as unenforceability defenses.

Sage further states that discovery is ongoing and Sage will supplement its response to this interrogatory as necessary pursuant to Fed. R. Civ. P. 26(e) after a substantial amount of discovery has been conducted. Sage expressly reserves the right to supplement, modify, or amend its responses contained herein.

3. For any asserted claim of the Patents-in-Suit that Defendant contends its Accused Product does not infringe, either directly, indirectly, literally, or under the doctrine of equivalents, provide the full bases for Defendant's contention, including by identifying each limitation in each claim that Defendant contends the Accused Product does not infringe, stating and explaining in full for each such limitation the entire legal and factual basis for the contention of non-infringement, identifying by production number all documents that support Defendant's

contention, and identifying all persons (expert or otherwise) with knowledge regarding Defendant's contentions and/or upon whom Defendant intends to rely to support its contentions.

RESPONSE TO INTERROGATORY 3:

In addition to the General Objections set forth above, Sage objects to this interrogatory as a premature contention interrogatory that has been served before a substantial amount of discovery has been completed. Discovery has just started in this case and there has been no deposition discovery. Sage objects to this interrogatory as premature because Plaintiff has not provided infringement contentions pursuant to Paragraph 7 of the Case Scheduling Order or in response to Sage's Interrogatory No. 1. Moreover, Plaintiff's Complaint and Amended Complaint is inadequate as it fails to explain how certain claim elements are purportedly satisfied. Indeed, Plaintiff has not even identified any particular asserted claims. Sage objects to this interrogatory as premature to the extent it seeks information that is the subject of expert discovery, which will be provided according to the Case Scheduling Order. Sage also objects to this interrogatory as premature because the parties have not yet proffered their proposed constructions of the asserted claims, and the Court's final claim constructions may affect Sage's non-infringement contentions. Sage objects to this interrogatory as overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs of the case. For example, Sage objects to this interrogatory as vague, overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs of the case to the extent the definition of "Accused Product" includes products other than Sage's PrimaFit® product identified in Plaintiff's Amended Complaint. Sage also objects to this interrogatory as overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs of the case to the extent it requests Sage provide non-infringement bases for unasserted claims (to date no asserted claims have been

identified) or accused products during a time period that predates the filing of the Complaint on August 12, 2019, or the Amended Complaint on October 2, 2019, which is not relevant since Plaintiff has not produced *prima facie* evidence that its products were marked and Plaintiff did not provide Sage notice of the Patents-In-Suit prior to the filing of the Complaint. Sage objects to this interrogatory as overly broad and unduly burdensome in that it requests Sage “stat[e] and explain[] in full for each such limitation the entire legal and factual basis for the contention of non-infringement.” Sage objects to this interrogatory because it contains multiple discrete parts, which should be counted as separate interrogatories pursuant to Fed. R. Civ. P. 33. The request that Sage identify “all documents” rather than representative documents or documents sufficient to show the relevant information is overly broad and unduly burdensome. That is particularly burdensome since all of Sage’s documents relating to the PrimaFit® product could potentially show why and how there is no infringement since many of the claim elements are missing.

Subject to and without waiving any general or specific objections, Sage incorporates the factual and legal bases for its allegations of non-infringement with respect to the PrimaFit® product identified in Sage’s Answer, Defenses, and Counterclaims (D.I. 12). For example, with respect to the 508 patent, the PrimaFit® product does not include several elements of the claims of the 508 patent, including at least the claimed “urine collection device” or “moisture-wicking article” adapted for use with such a device that includes “a container defining a chamber” (including one that “is closed at both ends”), “wherein the container is closed except for having an array of openings . . . through which urine can be drawn into the chamber,” “at least one outlet port through which urine can be drawn away from the chamber,” and “wherein an elongated exterior of the container is configured [and dimensioned] for enabling a moisture-wicking article to be secured over the array of openings of the container by wrapping the article over the array and securing the

wrapped article.” There is no person or entity that performs the method steps of “providing [the claimed] urine collection device,” “securing a moisture-wicking article over the array of openings by wrapping the article over the array and securing the article,” or “drawing the urine from the moisture-wicking material, through the array of openings and into the chamber from the disposed moisture-wicking article.” This is at least because the PrimaFit® product does not include a container, much less one that is closed or defines or has a chamber (much less one that is closed at both ends). It also does not include an array of openings (much less any article secured over the array by wrapping the article over it and securing the article) or a port through which urine is drawn away from any chamber. Nor does the PrimaFit® product have, for example, each of a container, an array of openings, and a moisture wicking article over such an array, all in the same device at the same time. There is also no direct infringement because there is no party that performs all of the steps of any claimed method claim, including the claimed “method of transporting urine voided from a person or animal.” For example, there is no party that performs the steps of “(a) providing a urine collection device . . . , (b) securing a moisture-wicking article over the array . . . (c) disposing the secured moisture-wicking article in contact with a region of the person . . . so that urine from the urethral opening is drawn into the moisture-wicking article; and (d) drawing the urine from the moisture-wicking material” Under Plaintiff’s own allegations, various unrelated parties and actors that do not act in concert would perform such steps, and Sage does not direct or control others’ performance.

With respect to the 376 patent, the PrimaFit® product does not include several elements of the claims of the 376 patent, including at least the claimed “apparatus” that includes “a fluid impermeable casing having [or defining] a fluid reservoir at a first end,” “a fluid impermeable casing defining a pliable fluid reservoir at a first end,” “a fluid impermeable layer,” and/or “a

membrane . . . supported on the support.” This is at least because the PrimaFit® product does not include at least a casing, much less an impermeable one or one that has or defines a fluid reservoir (or a pliable fluid reservoir). The PrimaFit® product also does not include a membrane supported on an inner support.

With respect to the 989 patent, the PrimaFit® product does not include several elements of the claims of the 989 patent, including at least the claimed “method” that includes “disposing in an operative relationship with the urethral opening of a female user a urine collecting apparatus” where the apparatus includes “a fluid impermeable casing having a fluid reservoir at a first end,” “a fluid impermeable layer,” and/or “a membrane . . . supported on the fluid permeable support.” This is at least because the PrimaFit® product does not include at least a casing, much less an impermeable one or one that has or defines a fluid reservoir. The PrimaFit® product also does not include a membrane supported on an inner support. The use of PrimaFit® product therefore does not infringe any of the claims.

Sage has also not contributorily infringed or induced infringement of any valid and enforceable claim of the Patents-In-Suit. Sage does not have the requisite specific intent to infringe or knowledge of infringement of the Patents-In-Suit required for inducement of infringement or contributory infringement. Sage does not offer to sell or sell within the United States or import into the United States any component knowing that it is especially made or especially adapted for use in infringement of the Patents-In-Suit.

Sage further states that discovery is ongoing and Sage will supplement its response to this interrogatory as necessary pursuant to Fed. R. Civ. P. 26(e) after further discovery has been conducted. Sage expressly reserves the right to supplement, modify, or amend its responses contained herein.

discovery has been conducted. Sage expressly reserves the right to supplement, modify, or amend its responses contained herein.

Dated: August 3, 2020

As to objections only,

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

Of Counsel:

Robert A. Surrette
Sandra A. Frantzen
Christopher M. Scharff
Bryce R. Persichetti
McAndrews, Held & Malloy, Ltd
500 West Madison Street
Chicago, IL 60661
(312) 775-8000
bsurrette@mcandrews-ip.com
sfrantzen@mcandrews-ip.com
cscharff@mcandrews-ip.com
bpersichetti@mcandrews-ip.com

/s/ Samantha G. Wilson

Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com

*Attorneys for Defendant and Counterclaim
Plaintiff Sage Products, LLC*

26857024.1

Exhibit 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PUREWICK CORPORATION,

Plaintiff and Counterclaim Defendant,

v.

SAGE PRODUCTS, LLC,

Defendant and Counterclaim Plaintiff.

C.A. No. 19-1508-MN

**CONTAINS CONFIDENTIAL
INFORMATION**

**DEFENDANT'S FOURTH SUPPLEMENTAL OBJECTIONS AND RESPONSES TO
PLAINTIFF'S INTERROGATORIES (NOS. 1-6, 8, AND 10)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendant and Counterclaim Plaintiff Sage Products, LLC (“Sage”) hereby supplements its objections and responses to Plaintiff’s Interrogatory Nos. 1-6, 8, and 10 as set forth herein.

GENERAL OBJECTIONS

1. Sage hereby incorporates its General and specific objections set forth in its prior responses to Plaintiff’s Interrogatories and Requests for the Production of Documents and Things.
2. Sage is willing to meet and confer to discuss its objections in a good faith attempt to resolve or narrow any differences between the parties.

INTERROGATORIES

1. For each month and year that the Accused Product has been sold or otherwise distributed by or for Defendant, identify on a monthly basis by customer the total number of units sold, gross revenues, net revenues, gross profits, net profits, and costs.

SECOND SUPPLEMENTAL RESPONSE TO INTERROGATORY 1:

3. For any asserted claim of the Patents-in-Suit that Defendant contends its Accused Product does not infringe, either directly, indirectly, literally, or under the doctrine of equivalents, provide the full bases for Defendant's contention, including by identifying each limitation in each claim that Defendant contends the Accused Product does not infringe, stating and explaining in full for each such limitation the entire legal and factual basis for the contention of non-infringement, identifying by production number all documents that support Defendant's contention, and identifying all persons (expert or otherwise) with knowledge regarding Defendant's contentions and/or upon whom Defendant intends to rely to support its contentions.

SECOND SUPPLEMENTAL RESPONSE TO INTERROGATORY 3:

In addition to the General Objections set forth above, Sage objects to this interrogatory as a contention interrogatory that has been served before a substantial amount of discovery has been completed including expert discovery. Sage objects to this interrogatory as premature because Plaintiff has not provided adequate infringement contentions pursuant to Paragraph 7 of the Case Scheduling Order (*see* D.I. 23 and 56) or in response to Sage's Interrogatory No. 1. Moreover, Plaintiff's Complaint, Amended Complaint, Second Amended Complaint, and Infringement Contentions are inadequate as they fail to explain how certain claim elements are purportedly satisfied. Sage objects to this interrogatory as premature to the extent it seeks information that is the subject of expert discovery, which will be provided according to the Case Scheduling Order. Sage objects to this interrogatory as overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs of the case. For example, Sage objects to this interrogatory as vague, overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs of the case to the extent the definition of "Accused Product" includes products other than Sage's PrimaFit® product and Sage's PrimoFit™ product identified in Plaintiff's Second Amended Complaint. Sage also objects to this interrogatory as overly broad, unduly burdensome, and seeking information not relevant to the claims or defenses of any party or proportional to the needs

of the case to the extent it requests Sage provide non-infringement bases for unasserted claims or accused products during a time period that predates the filing of the Complaint on August 12, 2019, the Amended Complaint on October 2, 2019, or the Second Amended Complaint on May 18, 2020, which is not relevant since Plaintiff has not produced *prima facie* evidence that its products were marked and Plaintiff did not provide Sage notice of the Patents-In-Suit prior to the filing of the complaints. Sage objects to this interrogatory as overly broad and unduly burdensome in that it requests Sage “stat[e] and explain[] in full for each such limitation the entire legal and factual basis for the contention of non-infringement.” Sage objects to this interrogatory because it contains multiple discrete parts, which should be counted as separate interrogatories pursuant to Fed. R. Civ. P. 33. The request that Sage identify “all documents” rather than representative documents or documents sufficient to show the relevant information is overly broad and unduly burdensome. That is particularly burdensome since all of Sage’s documents relating to the PrimaFit® product and/or the PrimoFit™ product could potentially show why and how there is no infringement since many of the claim elements are missing. Sage preliminarily incorporates documents that were produced pursuant to its core technical document productions that depict the structure, function, and operation of the accused PrimaFit® product and the PrimoFit™ product including SAGE1-477 and SAGE21399-489. Sage further incorporates technical documents discussed and marked during the deposition of Brett Blabas as well as documents that were provided by counsel for PureWick in the Blabas binder as part of the deposition to the extent that they relate to the current version of the PrimaFit® product including, for example, Blabas Tabs 7, 10, 17, 19, 20, 22, 39, and 71.

Subject to and without waiving any general or specific objections, Sage incorporates the factual and legal bases for its allegations of non-infringement with respect to the PrimaFit® product

identified in Sage's Answer, Defenses, and Counterclaims to Plaintiff's Amended Complaint (D.I. 12). Sage also hereby incorporates factual and legal bases for its allegations of non-infringement with respect to the PrimaFit® product and the PrimoFit™ product identified in its Answer, Defenses, and Counterclaims to Plaintiff's Second Amended Complaint (D.I. 53). Sage also disclosed the factual and legal bases for its allegations of non-infringement with respect to the PrimaFit® product and the PrimoFit™ product in its letter from Robert A. Surrette to Steven C. Cherny on May 15, 2020, which is hereby incorporated by reference. Sage further incorporates its response to Interrogatory No. 2. Moreover, PureWick's infringement contentions (served on April 2, 2020 and July 17, 2020) do not provide an adequate explanation of how Sage's and PrimaFit® PrimoFit™ products infringe the Patents-In-Suit. For example, PureWick has failed to provide any evidence of doctrine of equivalents infringement including that any element is present under that doctrine (for example, any evidence that the missing elements are present through an equivalent).

For example, with respect to the 508 patent, the Asserted Claims are Claims 1, 3-8, and 17-19. The PrimaFit® product does not include several elements of the claims of the 508 patent, including at least the claimed "urine collection device" or "moisture-wicking article" adapted for use with such a device that includes "a container defining a chamber" (including one that "is closed at both ends"), "wherein the container is closed except for having an array of openings . . . through which urine can be drawn into the chamber," "at least one outlet port through which urine can be drawn away from the chamber," and "wherein an elongated exterior of the container is configured [and dimensioned] for enabling a moisture-wicking article to be secured over the array of openings of the container by wrapping the article over the array and securing the wrapped article." There is no person or entity that performs the method steps of "providing [the claimed] urine collection device," "securing a moisture-wicking article over the array of openings by wrapping the article

over the array and securing the article,” or “drawing the urine from the moisture-wicking material, through the array of openings and into the chamber from the disposed moisture-wicking article.” This is at least because the PrimaFit® product does not include a container, much less one that is closed or defines or has a chamber (much less one that is closed at both ends). It also does not include an array of openings (much less any article secured over the array by wrapping the article over it and securing the article) or a port through which urine is drawn away from any chamber. Nor does the PrimaFit® product have, for example, each of a container, an array of openings, and a moisture wicking article over such an array, all in the same device at the same time. Moreover, Plaintiff has not established that the alleged absorbent fabric in the PrimaFit® is a “moisture-wicking article” as that term has been construed. There is also no direct infringement because there is no party that performs all of the steps of any claimed method claim, including the claimed “method of transporting urine voided from a person or animal.” For example, there is no party that performs the steps of “(a) providing a urine collection device . . . , (b) securing a moisture-wicking article over the array . . . (c) disposing the secured moisture-wicking article in contact with a region of the person . . . so that urine from the urethral opening is drawn into the moisture-wicking article; and (d) drawing the urine from the moisture-wicking material” Under Plaintiff’s own allegations, various unrelated parties and actors that do not act in concert would perform such steps, and Sage does not direct or control others’ performance. Sage does not infringe the asserted dependent claims of the 508 patent at least because the independent claims are not infringed. In addition, for example, Sage does not infringe the dependent claims at least because the accused PrimaFit® product does not have a “moisture-wicking article [that] has the moisture-wicking characteristic of a paper towel,” does not include a “vacuum pump for drawing the urine through the array of openings and into the chamber from the disposed moisture-wicking article,” and does

not have “[a] moisture-wicking article . . . wherein the article is dimensioned for being secured over the array of openings by the application of elastic bands about the moisture-wicking article at opposite ends of the array of openings.”

With respect to the 376 patent, the Asserted Claims are Claims 1, 4-6, 9, and 11-13. Claims 7, 8, and 14 have been withdrawn. The PrimaFit® product does not include several elements of the claims of the 376 patent, including at least the claimed “apparatus” that includes “a fluid impermeable casing having [or defining] a fluid reservoir at a first end,” “a fluid impermeable casing defining a pliable fluid reservoir at a first end,” “a fluid impermeable layer,” and/or “a membrane . . . supported on the support.” This is at least because the PrimaFit® product does not include at least a casing, much less an impermeable one or one that has or defines a fluid reservoir (or a pliable fluid reservoir). The PrimaFit® product also does not include a support disclosed in a casing or a membrane supported on an inner support. As explained in prior correspondence, which has been incorporated herein, the PrimaFit® is not configured to “be retained in position on the user solely by frictional engagement with and/or between the labia and/or other portions of the area of the user’s body surrounding the urethral opening.” Indeed, to the contrary, it is held in place a number of other ways as our correspondence to PureWick has pointed out. Sage does not infringe the asserted dependent claims of the 376 patent at least because the independent claims are not infringed. In addition, for example, Sage does not infringe the dependent claims at least because the accused PrimaFit® product not contain “a fabric sleeve disposed around the support,” the claimed apparatus “wherein the support and casing are substantially cylindrical,” and the claimed container with “an elongated opening.” Plaintiff has not even attempted to establish that there is a fabric sleeve, and furthermore neither the alleged “fluid impermeable casing” nor the alleged support are substantially cylindrical whatsoever. Further, PureWick has not provided

evidence that the accused PrimaFit® product contains a “support . . . formed of spun plastic and the membrane is formed of ribbed knit fabric” and the accused product is not “configured to be retained in position on the user via engagement between the first end of the casing and a user's perineum.” Moreover, Plaintiff has not established that the alleged absorbent fabric in the PrimaFit® is a “wicking material” as that term has been construed.

With respect to the 989 patent, the Asserted Claims are Claims 1-3 and 5-6. Claim 4 has been withdrawn. Many of the elements are duplicative of the 376 patent and Sage's statements regarding that patent are incorporated herein. The PrimaFit® product does not include several elements of the claims of the 989 patent, including at least the claimed “method” that includes “disposing in an operative relationship with the urethral opening of a female user a urine collecting apparatus” where the apparatus includes “a fluid impermeable casing having a fluid reservoir at a first end,” “a fluid impermeable layer,” and/or “a membrane . . . supported on the fluid permeable support.” This is at least because the PrimaFit® product does not include at least a casing, much less an impermeable one or one that has or defines a fluid reservoir. The PrimaFit® product also does not include a membrane supported on an inner support. The use of PrimaFit® product therefore does not infringe any of the claims. Sage does not infringe the asserted dependent claims of the 989 patent at least because the independent claims are not infringed. In addition, for example, Sage does not infringe the dependent claims because the accused product does not include the claimed container with “an elongated opening” or “the fluid permeable support and fluid permeable casing are cylindrical.” PureWick's final infringement contentions do not allege infringement of Claim 4, thus, Claim 5 which depends on Claim 4 cannot be infringed as a matter of law. Moreover, there is also no direct infringement because PureWick has not established that there is any party that performs all of the steps of any claimed method claim. For example,

PureWick has not established that there is any party that performs the steps of “disposing …a urine collection apparatus” and also performs the steps of “allowing the urine discharged…to be received [in the device]”, and “allowing the received urine to be withdrawn.” Under Plaintiff’s own allegations, various unrelated parties and actors that do not act in concert would perform such steps, and Sage does not direct or control others’ performance. This is also true for the steps of the “fluidically coupling the fluid discharge end of the tube [to vacuum]”, “allowing urineto be received in the fluid receptacle,” and “disposing in operative relationship . . . a second urine collecting apparatus.” For each claim, PureWick has failed to show that any single party performs all of these steps. Moreover, despite its burden, PureWick has provided no evidence of direct infringement whatsoever even with disparate parties.

Again, additional and full reasons for non-infringement were set out fully in Sage’s letter from Robert A. Surrette to Steven C. Cherny on May 15, 2020, which is hereby incorporated by reference. That letter is repeated here for reference:

On May 15, 2020, Sage sent a detailed letter to counsel for PureWick (further referenced below), explaining in detail numerous deficiencies in PureWick’s allegations and asking PureWick to drop its case. That letter is incorporated herein. PureWick did not drop its case but instead pressed on with its baseless allegations. In that May 15 letter, Sage explained:

“I write on behalf of Sage Products to request that PureWick Corporation withdraw the above-referenced case in light of the clear non-infringement and invalidity of U.S. Pat. Nos. 8,287,508, 10,226,376, and 10,390,989. As you know, PureWick has alleged willful infringement of claims of each of these patents by Sage’s PrimaFit® external urine management system for females. We have reviewed the infringement contentions served by PureWick’s outside counsel on April 3, 2020. As explained below, PureWick’s allegations are unsustainable. We further

believe that the claims being made about U.S. Patent No. 10,376,407 are clearly unviable in view of the clear disclaimers in that patent's prosecution history. Continued maintenance of the lawsuit by PureWick would render this case "exceptional" (to the extent it has not already), entitling Sage to attorneys' fees and other relief.

U.S. Pat. No. 8,287,508

PureWick's infringement allegations with respect to the asserted claims of the '508 patent are untenable and cannot be supported by any reasonable interpretation of the claims. In many instances, PureWick has either skipped or glossed over claim limitations and taken positions that are opposite of what it represented in the specification or to the Patent Office during patent prosecution. Below are just examples of some of these issues.

PureWick has no credible argument that the PrimaFit® has a "*container defining a chamber for collecting urine*," a "*closed*" container, or a container having an "*array of openings*"—elements that are required by each of the asserted claims of the '508 patent. PureWick's reliance on the sieve-like batting in the PrimaFit® for these elements is frivolous, given that the PrimaFit® batting does not contain any liquid, has no role in defining any chamber, is open at one end (as is the entire PrimaFit® device), and provides no array of openings. PureWick's apparent argument is literally akin to saying that a sieve is a container, which is the opposite of a container. In fact, in PureWick's infringement contentions, PureWick simply skipped the "chamber" requirement and the "closed" requirement, failing to point to anything in PrimaFit® that satisfies these limitations. This is improper.

Equally meritless is PureWick's allegation that PrimaFit® has a "*moisture-wicking article*" that is "*secured over the array of openings of the container by wrapping the article over the array and securing the wrapped article*" (which is required by all of the asserted '508 patent

claims). PureWick never explains how PrimaFit® has a “wrapped” article over any openings or how any such wrapped article is “secured” as claimed. Moreover, PureWick’s allegations that PrimaFit® has any “article” “secured over the array of openings of the container by wrapping . . .” directly contradicts statements that PureWick made during the prosecution of the ‘508 patent about that very limitation to overcome prior art.

In dependent claim 18, PureWick appears to allege equivalents infringement, knowing that the element is not literally present. PureWick alleges that PrimaFit® somehow satisfies the claim’s requirement of “*elastic bands*”—even though PureWick identifies no elastic bands (or equivalents). Moreover, PureWick expressly stated in the patent specification that adhesive tape is not an “elastic band.” Any attempt to recapture this non-claimed embodiment through the doctrine of equivalents flouts the law.

By lodging unfounded allegations, PureWick is needlessly escalating the time spent by Sage searching for and reviewing prior art for these claims, including dependent claims, when there is no colorable basis for alleging infringement. That is particularly harmful here where our invalidity contentions are due on May 29, and PureWick forces Sage to spend money and effort on claims that are clearly not infringed.

U.S. Pat. Nos. 10,226,376, and 10,390,989

PureWick’s infringement allegations with respect to the asserted claims of the ‘376 and ‘989 patents are equally untenable. PureWick again repeats its pattern of taking positions that are the opposite of what the patents and prosecution history disclose and simply skipping over claim elements.

For example, the asserted claims of these two patents require both a “*fluid impermeable casing*” and one “*having*” or “*defining*” a “*fluid reservoir*.” The patents distinguish between a device with a “backing” and a device with a “casing.” Yet PureWick points to no structure in the accused device that is a “casing,” much less one having or defining a fluid reservoir.

With respect to the claimed “*fabric sleeve*” in dependent claim 4 of the ‘376 patent, PureWick erroneously asserts that the complete opposite of the claim limitation somehow satisfies that limitation. There is no credible argument that PrimaFit® has a “fabric sleeve.” The ‘376 and ‘989 patents distinguish between a “fabric sleeve” that extends about the device and a fabric “sheet”.

Likewise, there is no credible argument that PrimaFit® satisfies the requirement in dependent claims 11 and 12 of the ‘376 patent that the apparatus “*be retained in position on the user solely by frictional engagement with and/or between the labia and/or other portions of the area of the user's body surrounding the urethral opening*.” PrimaFit® is not held in place solely by frictional engagement with the labia or any area surrounding the urethral opening. Rather, PrimaFit® uses multiple means to keep the device in place, including adhesive wings and other structures.

We again ask that you drop these claims, including the clearly non-infringed dependent claims, as it is inappropriately escalating the work that needs to be done in assessing and reviewing prior art. ***”With respect to the 407 patent, the Asserted Claims are Claims 1, 2, 5, 7-9, and 13-15. Claims 10, 11, and 16 have been withdrawn. The PrimoFit™ product does not include several elements of the claims of the 407 patent including at least the claimed “chamber of void space positioned within the interior portion of the device between the flexible layer of porous material and the flexible layer of impermeable material,” “the chamber being defined at least partially by

the second side of the porous material and the flexible layer of impermeable material,” the chamber “configured to collect urine for transport,” the chamber “having a port for receiving a tube . . . ,” “a receptacle . . . dimensioned and configured to receive a head of the penis . . . ,” “the flexible layer of impermeable material . . . dimensioned and configured to shape the receptacle to receive the head of the penis . . . ,” “the receptacle . . . configured to draw urine flowing from said penis through the flexible wicking material and the porous material into the chamber . . . ,” a “chamber positioned substantially opposite to the opening,” a “port being positioned substantially opposite to the opening of the cavity,” or a “port extending through the impermeable material.” This is at least because the PrimoFit™ does not have the claimed chamber or receptacle. For example, the PrimoFit™ contains material between the alleged porous material and alleged impermeable layer and the alleged receptacle is not configured as claimed. PureWick’s infringement allegations are wholly deficient. For example, there is no “chamber” or “void space” as alleged by PureWick in its Infringement Contentions, and the alleged chamber is not defined by any “side” of any alleged porous material or impermeable material. In addition, the alleged “wicking material” is not a wicking material as the Court has construed that term. Further, neither the alleged port nor the alleged chamber that PureWick identified are “positioned substantially opposite” to the alleged opening. The PrimoFit™ therefore does not infringe any claims of the 407 patent. Sage does not infringe the asserted dependent claims of the 407 patent at least because the independent claims are not infringed. In addition, for example, Sage does not infringe the dependent claims at least because the accused PrimoFit™ product does not have the claimed “lip,” “gauze,” “receptacle defined at least partially by the wicking material . . . and being shaped to receive at least a head of a penis,” “void space positioned between the portion of the flexible porous material and the [sic] portion of the impermeable material defining the chamber,” “portion of the porous material

defining the chamber,” or “a port extending through the portion of the impermeable material to the chamber, the port being positioned substantially opposite to the opening of the cavity.”

Again, additional details regarding how Sage could not infringe the 407 Patent were set forth fully in the briefing on the motion to amend (D.I. 43) and related arguments, which are hereby incorporated by reference. A portion of that is repeated here for reference (and was also referenced in Interrogatory No. 2):

Sage explained in detail why there could be no infringement of the 407 patent by PrimoFit® as a matter of law (including under PureWick’s own allegations) and those facts and arguments are incorporated herein by reference. (D.I. 43.) Sage explained: “[p]rosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution.” *Amgen v. Coherus BioSciences*, 931 F.3d 1154, 1159 (Fed. Cir. 2019). Similarly, prosecution disclaimer precludes a patentee from “recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Omega Eng’g v. Raytek*, 334 F. 3d 1314, 1323 (Fed. Cir. 2003). For disclaimer or argument-based estoppel to attach, “precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.” *Id.* And, when there are claim amendments (as here), the “amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim” for estoppel purposes. *Festo v. Shoketsu*, 535 U.S. 722, 740 (2002).

...Here, prosecution history estoppel and disclaimer likewise bar PureWick’s infringement claim under the 407 Patent as a matter of law. During prosecution, in addressing added claim language that requires a urine “chamber . . . defined at least partially by . . . the porous material and . . . impermeable material,” PureWick clearly and unmistakably surrendered male catheters

with materials between the “porous” and “impermeable” layer [as that term was clarified by the Court], a feature present in the accused device.

Specifically, in 2016, PureWick filed its original claims, which generally related to a male external catheter with several features including a “porous material” layer, an “impermeable material” layer, and a “chamber” between those layers. (D.I. 43, Ex. H at 23.) But the PTO rejected those claims as anticipated by the Suzuki and Kuntz prior art. (*Id.* at 133-134; Exs. I and J.) PureWick then amended its claims to require that the “chamber” be “defined at least partially by the second side of the porous material and the layer of impermeable material.” (*Id.* at 149.) The PTO again rejected the claims as anticipated by Suzuki and Kuntz, noting that those references disclosed a chamber between the porous and impermeable layers. (*Id.* at 279, 281.)

After receiving that rejection, PureWick clearly and unmistakably distinguished the prior art by repeatedly arguing that, if a device had materials between the porous and impermeable layers (such as pad core or space filler material), the chamber was not “defined partially by the . . . porous material and the . . . impermeable material” because of the material between the layers:

Assuming, *arguendo*, the lower backing layer 36 of Kuntz discloses the impermeable layer, the absorptive pad 12 of Kuntz discloses the porous material of claim 1, and the central bore 22 (asserted by the PTO to disclose the chamber of claim 1) is not defined at least partially by the second side of the absorptive pad 12 and the lower backing layer 36. For example, in Figs. 2 and 3 of Kuntz (provided below for reference), the impermeable material 36a is separated from the central bore 22a by the pad core 34.

(*Id.* at 331; *see also* 317.) PureWick repeated this disclaimer while addressing Suzuki. (*Id.* at 327 (“[T]he surface material 14, [other items], and the air impermeable sheet 21 all appear to be positioned between the space retention material 23 and the porous surface sheet 15. Accordingly, Suzuki does not appear to disclose ‘the chamber being defined at least partially by the . . . porous material and the . . . layer of impermeable material,’ as recited in . . . claim 1.) These arguments

were repeated, yet again, in a later response. (*Id.* at 357-358, 364.) The arguments were accepted by the Examiner, and claims were allowed with the arguments noted. (*Id.* at 387, 394.)

The claim has now been construed. Yet, PureWick still alleges that this exact disclaimed configuration infringes, which is impermissible as a matter of law. Specifically, PureWick alleges that a layer of material shown in Paragraph 114 on the top of the accused device is a “porous layer” and a layer shown in Paragraph 116 on the bottom of the device is an “impermeable layer.” (D.I. 44.) The bottom image in Paragraph 118 purports to depict a gap between the top and bottom of the device (highlighted in red by Plaintiff, presumably the “chamber”). (*Id.*) But, as can be seen in Plaintiff’s own image, there is material between what Plaintiff has identified as the “porous layer” (on top) and the “impermeable layer” (on bottom). This configuration cannot infringe as a matter of law and thus Plaintiff’s claim is barred.

PureWick’s subsequent “infringement contentions” likewise did not provide a good faith explanation of how Sage’s PrimoFit™ product could possibly infringe. In its Final Infringement Contentions, it appears that PureWick now alleges infringement under the doctrine of equivalents for the following claim elements: 508 patent claim 18, “wherein the article is dimensioned for being secured over the array of openings by the application of elastic bands about the moisture-wicking article at opposite ends of the array of openings;” 407 patent claim 2, “wherein the flexible layer of impermeable material extends beyond covering the other side of the flexible layer of porous material and hence inward over the receptacle to thereby provide a lip for retaining urine within the receptacle;” and 407 patent claim 5, “wherein the flexible wicking material includes gauze.” As a preliminary matter, PureWick’s analysis is untimely and PureWick is barred from alleging doctrine of equivalents because it is not alleged in its Complaint. In any case, PureWick has not established that the differences are insubstantial as there are substantially differences and

the specification distinguishes between these embodiments. Moreover, doctrine of equivalents is not available for any of those elements under the doctrine of prosecution estoppel including because narrowing amendments were made for purposes of patentability. In any case, PureWick's arguments result in claim vitiation and none of the substitute elements perform the substantially the same function, in substantially the same way, to achieve substantially the same result, as the element in the patent claim.

Sage has also not contributorily infringed or induced infringement of any valid and enforceable claim of the Patents-In-Suit. Sage does not have the requisite specific intent to infringe or knowledge of infringement of the Patents-In-Suit required for inducement of infringement or contributory infringement. Sage does not offer to sell or sell within the United States or import into the United States any component knowing that it is especially made or especially adapted for use in infringement of the Patents-In-Suit. Notably, PureWick has failed to provide any evidence of indirect infringement in response to any of Sage's interrogatories.

Sage further states that discovery is ongoing and Sage will supplement its response to this interrogatory as necessary pursuant to Fed. R. Civ. P. 26(e) after further discovery has been conducted. Sage expressly reserves the right to supplement, modify, or amend its responses contained herein. Moreover, Sage has only recently received PureWick's Final Infringement Contentions and its review of that document is ongoing and Sage may supplement this response in further response to that document.

4. State the basis for any contention that any infringement of the Patents-in-Suit was not or will not be willful, including identifying all facts, literature, or other documents or evidence that Defendant asserts support its contention, and identifying each person with knowledge of such facts.

Dated: March 16, 2021

As to objections only,

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

Of Counsel:

Robert A. Surrette
Sandra A. Frantzen
Christopher M. Scharff
Ryan J. Pianetto
Bryce R. Persichetti
McAndrews, Held & Malloy, Ltd
500 West Madison Street
Chicago, IL 60661
(312) 775-8000
bsurrette@mcandrews-ip.com
sfrantzen@mcandrews-ip.com
cscharff@mcandrews-ip.com
rpianetto@mcandrews-ip.com
bpersichetti@mcandrews-ip.com

/s/ Samantha G. Wilson

Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com

*Attorneys for Defendant and Counterclaim
Plaintiff Sage Products, LLC*

Exhibits 3-15
REDACTED IN THEIR
ENTIRETY